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companies under the Bank Holding Company Act.

Board of Governors of the Federal Reserve System, May 27, 1992.

William W. Wiles,

*Secretary of the Board.*

[FR Doc. 92-12798 Filed 6-1-92; 8:45 am]

BILLING CODE 6210-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Alcohol, Drug Abuse, and Mental Health Administration

### Request for Applications: Capacity Expansion Program

**AGENCY:** Alcohol, Drug Abuse, and Mental Health Administration, HHS.

**ACTION:** Correction notice.

**SUMMARY:** Public notice was given in the Federal Register on April 20, 1992, Volume 57, No. 76, on pages 14407-14418 that the Office for Treatment Improvement (OTI), in its role of implementing demand reduction programs under the Office of National Drug Control Policy (ONDCP) National Drug Control Strategy is soliciting State applications for the creation of new addiction treatment capacity in high-incidence jurisdictions of greatest need under its FY 1992 Treatment Capacity Program.

An example was inadvertently given in the Availability of Non-Federal Matching Funds section of the notice (page 14411, first column) that non-Federal (State) Medicaid contributions are allowable as a non-Federal match. Non-Federal (State) Medicaid contributions may not be used as a match, thus the second sentence of the section has been corrected to read:

Matching resources may be financial or in-kind, must be derived from non-Federal sources (e.g., State or sub-state non-Federal revenues, foundation grants), and must constitute at least 10 percent of the total annual costs (direct and indirect) of the proposed project(s) for which the assurance is provided.

Dated: May 27, 1992.

Joseph R. Leone,

*Associate Administrator for Management.*

[FR Doc. 92-12843 Filed 6-1-92; 8:45 am]

BILLING CODE 4160-20-M

## Food and Drug Administration

**[Docket No. 92E-0156]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; Mivacron®

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Mivacron® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** John S. Ensign, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and

an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Mivacron®. Mivacron® (mivacurium chloride) is indicated for inpatients and outpatients, as an adjunct to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Mivacron® (U.S. Patent No. 4,761,418) from Burroughs Wellcome Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated April 21, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Mivacron® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Mivacron® is 2,755 days. Of this time, 2,245 days occurred during the testing phase of the regulatory review period, while 510 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective*: July 7, 1984. FDA has verified the applicant's claim that the investigational new drug application became effective on July 7, 1984.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: August 30, 1990. FDA has verified the applicant's claim that the new drug application (NDA) for Mivacron® (NDA 20-098) was submitted on August 30, 1990.

3. *The date the application was approved*: January 22, 1992. FDA has verified the applicant's claim that NDA 20-098 was approved on January 22, 1992.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 172 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before August 3, 1992, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 30, 1992, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 27, 1992.

**Stuart L. Nightingale,**

*Associate Commissioner for Health Affairs.*

[FR Doc. 92-12845 Filed 6-1-92; 8:45 a.m.]

BILLING CODE 4160-01-F

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[Docket No. 92E-0133]

## Determination of Regulatory Review Period for Purposes of Patent Extension; Supprelin®

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Supprelin® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** John S. Ensign, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Supprelin®. Supprelin® (histrelin acetate) is indicated for the control of the biochemical and clinical manifestations of central precocious puberty. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Supprelin® (U.S. Patent No. 4,244,946) from The Salk Institute for Biological Studies, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated March 25, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Supprelin® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Supprelin® is 2,876 days. Of this time, 1,930 days occurred during the testing phase of the regulatory review period, while 946 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* February 8, 1984. No investigational new drug application (IND) effective date was stated in the application for patent extension. FDA records indicate that the IND effective date was February 8, 1984, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* May 22, 1989. The applicant claims May 19, 1989, as the date the new drug application (NDA) for Supprelin® (NDA 19-836) was filed. However, FDA records indicate that NDA 19-836 was submitted on May 22, 1989.

3. *The date the application was approved:* December 24, 1991. FDA has verified the applicant's claim that NDA 19-836 was approved on December 24, 1991.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,752 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before August 3, 1992, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 30, 1992, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.